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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/403,627	05/31/2000	JEAN-GERARD GUILLET	97AECNRIMM	7512

23869 7590 07/15/2002

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EXAMINER

DECLoux, AMY M

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 07/15/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/403,627

Applicant(s)

GUILLET ET AL.

Examiner

Amy M. DeCloux

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-113 is/are pending in the application.
- 4a) Of the above claim(s) 22-54, 61-68, 70-73 and 76-113 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21, 55-60, 69, 74 and 75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 May 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group VI, claims 55-60 and 74-75 in Paper No. 14, filed 4-26-02, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Because no art was found on the elected species, the species requirement has been withdrawn. Also independent claims 21 and 69 have been rejoined with Group VI, but will only be examined to the extent of the elected invention.

2. Claims 22-54, 61-68, 70-73 and 76-113 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 14, filed 4-26-02.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Oath/Declaration

4. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Specifically said alterations appear in the address of the second, fifth and seventh inventors.

Information Disclosure Statement

5. The information disclosure statement filed 12-17-99, Paper No.3, fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered. Specifically, WO 95/24916 has been considered only to the extent of the Abstract.

Drawings

6. New formal drawings are required in this application because of the reasons in the PTO Form 928 attached to the instant office action. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsman.

2. Corrections other than Informalities Noted by Draftsman on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsman, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

3. Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

Priority

7. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
9. Claims 21, 55-60, 69 and 74-75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
Claims 21 and 55-60 are indefinite in their recitation of non-elected subject matter specifically recited in claim 21, and claims 69 and 74-75 are indefinite in their recitation of non-elected subject matter specifically recited in claim 21.
10. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
11. Claims 21, 55-60, 69 and 74-75 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are drawn to a peptide analog wherein the parent peptide is a peptide of the AIDS virus including the peptides NEF 84-92 and GAG 77-85 wherein at least one of the peptide bonds is modified, specifically being substituted with CH₂-NH or CHOH-NH, and a vaccine composition thereof.

The instant specification discloses on page that said peptide is an agonist or partial agonist of a receptor which recognizes the antigen of the parent peptide. The instant specification discloses on page 6 that peptide bond replacements include CH₂-NH, but does not disclose a CHOH-NH bond replacement. Therefore, without further guidance from the instant specification it would require undue experimentation for one of skill to predict which peptide analog would act as an agonist for the parent peptide.

Though the instant specification discloses on page 6 that peptide bond replacement includes CH₂-NH can replace one or more bonds and discloses invitro data showing that some peptide analogs of MART-1 and M58-66 containing one substituted CH₂NH bond were able to bind a single HLA-A2 molecule (depending on the position of said bond) and were able to induce lysis by HLA-A2 restricted CTL of target T2 cells incubated with some of the peptide analogs, the instant specification provides insufficient guidance and direction of the effect of the location of said bonds on the ability of said peptide analogs to be effective agonists or partial

Art Unit: 1644

agonists of the parent peptide. That the position of said replacement CH₂NH bond causes a variation in the immune response is demonstrated by Benkirane et al (IDS). Benkirane et al teaches that the ability of a recombinant single chain Kd molecule to bind a peptide containing a CH₂NH bond, relative to the parent peptide varied according to the position of the methyleneamino bond (see entire article including page 33218, column 2, last three sentences and page 33219, column 1, lines 1-5). Because Benkirane teaches that immune recognition of a peptide varies with the placement of a methyleneamino bond, it would require undue experimentation for one of skill to predict which amino acid peptide bond in the recited peptides could be replaced, while maintaining the agonist activity of the peptide, or maintaining the effectiveness of said altered peptide in a vaccine composition for the prevention or treatment of a condition associated with a cell mediated immune response involving CTLs. It is noted that the instant specification lacks any in vivo working examples of any vaccine compositions comprising any peptide analogs including the recited AIDS GAG and NEF peptide analogs, nor are any in vivo examples disclosed. In view of the lack of enablement for even the most narrow claims interpreted in an in vitro sense, the broader claims encompassing any peptide analog of any peptide from HIV comprising any modification of any peptide bond are also not enabled, nor is a vaccine composition comprising any said peptide analog, for the prevention or treatment of any condition associated with any cell mediated immune response involving any cytotoxic T lymphocytes, as recited in the instant claims.

12. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 305-3014 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, PhD,
Patent Examiner, Group 1640

July 13, 2002

Amy DeCloux

7-13-02